



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0594; FRL-10970-01-OCSP]

Various Fragrance Components in Pesticide Formulations; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of various fragrance components listed in Unit II of this document when they are used as inert ingredients in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils when the end-use concentration does not exceed 100 parts per million (ppm). Verto Solutions, on behalf of The Clorox Company, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the establishment of exemptions from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of these various fragrance components, when used in accordance with the terms of the exemptions.

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0594, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution

Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: RDNRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file

your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2019-0594 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0594, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets#express>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Petition for Exemption

In the *Federal Register* of February 11, 2020 (85 FR 7708) (FRL-10005-02), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide

petition (PP IN-11316) by Verto Solutions on behalf of The Clorox Company, 4900 Johnson Dr., Pleasanton, CA 94588. The petition requested that 40 CFR 180.940(a) be amended by establishing exemptions from the requirement of a tolerance for residues of 1,3,3-trimethyl-2-norbornanyl acetate (CAS Reg. No. 13851-11-1); 1H-Indole (CAS Reg. No. 120-72-9); 2,6-Octadien-1-ol, 3,7-dimethyl-, (Z)- (CAS Reg. No. 106-25-2); 2-Decenal (CAS Reg. No. 3913-71-1); 2-Hexenal, (2E)- (CAS Reg. No. 6728-26-3); 2-Methyl-3-(p-isopropylphenyl)propionaldehyde (CAS Reg. No. 103-95-7); 2-Methyl-4-phenyl-2-butanol (CAS Reg. No. 103-05-9); 2-Phenylpropionaldehyde (CAS Reg. No. 93-53-8); 2-Phenylpropionaldehyde dimethyl acetal (CAS Reg. No. 90-87-9); α -Pinene (CAS Reg. No. 80-56-8); β -Caryophyllene (CAS Reg. No. 87-44-5); Bicyclo(2.2.1)heptan-2-ol, 1,3,3-trimethyl- (CAS Reg. No. 1632-73-1); Bicyclo(2.2.1)heptan-2-ol, 1,7,7-trimethyl-,propanoate, exo- (CAS Reg. No. 2756-56-1); Bicyclo[3.1.1]heptane, 6,6-dimethyl-2-methylene- (CAS Reg. No. 127-91-3); Butanoic acid, 1,1-dimethyl-2-phenylethyl ester (CAS Reg. No. 10094-34-5); Celery seed oil (CAS Reg. No. 8015-90-5); Citronellal (CAS Reg. No. 106-23-0); Cyclohexene, 1-methyl-4-(1-methylethylidene)- (CAS Reg. No. 586-62-9); Dimethylbenzylcarbonyl acetate (CAS Reg. No. 151-05-3); Elemi oil (Canarium spp.) (CAS Reg. No. 8023-89-0); Ethyl (2E,4Z)-2,4-decadienoate (CAS Reg. No. 3025-30-7); Galbanum oil (Ferula spp.) (CAS Reg. No. 8023-91-4); γ -Terpinene (CAS Reg. No. 99-85-4); Isoborneol (CAS Reg. No. 124-76-5); Isobornyl acetate (CAS Reg. No. 125-12-2); Labdanum oil (Cistus spp.) (CAS Reg. No. 8016-26-0); laevo-Bornyl acetate (CAS Reg. No. 5655-61-8); Mace oil (Myristica fragrans Houtt.) (CAS Reg. No. 8007-12-3); Methyl 2-nonenoate (CAS Reg. No. 111-79-5); Methyl 2-nonynoate (CAS Reg. No. 111-80-8); Methyl anthranilate (CAS Reg. No. 134-20-3); Methyl heptine carbonate (CAS Reg. No. 111-12-6); Methyl N-methylanthranilate (CAS Reg. No. 85-91-6); Nerolidol (isomer unspecified) (CAS Reg. No. 7212-44-4); Nona-2-trans-6-cis-dienal (CAS Reg. No. 557-48-2); Oil of lemon (CAS Reg. No. 8008-56-8); Oil of lemongrass (CAS Reg. No. 8007-02-1); Oils, clove (CAS Reg. No. 8000-34-8); Oils, ginger (CAS Reg. No.

8007-08-7); Oils, grapefruit (CAS Reg. No. 8016-20-4); Oils, lime (CAS Reg. No. 8008-26-2); Oils, orange, sweet, terpene-free (CAS Reg. No. 68606-94-0); Olibanum oil (Boswellia spp.) (CAS Reg. No. 8016-36-2); Oxacycloheptadec-10-ene-2-one (CAS Reg. No. 28645-51-4); p-Cymene (CAS Reg. No. 99-87-6); Phenol, 2-methoxy-4-(2-propenyl)- (CAS Reg. No. 97-53-0); p-Methylanisole (CAS Reg. No. 104-93-8); Tangerine oil (Citrus reticulata blanco) (CAS Reg. No. 8008-31-9); Ylang-ylang oils (CAS Reg. No. 8006-81-3); when used as inert ingredients (fragrance components) in pesticide formulations applied to food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment with end-use concentrations not to exceed 100 ppm. That document referenced a summary of the petition prepared by Verto Solutions on behalf of The Clorox Company, which is available in the docket, <https://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe”

to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. When making a safety determination for an exemption for the requirement of a tolerance, FFDCA section 408(c)(2)(B) directs EPA to consider the considerations in section 408(b)(2)(C) and (D). Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....” Section 408(b)(2)(D) lists other factors for EPA’s consideration in making safety determinations, *e.g.*, the validity, completeness, and reliability of available data, nature of toxic effects, available information concerning the cumulative effects of the pesticide chemical and other substances with a common mechanism of toxicity, and available information concerning aggregate exposure levels to the pesticide chemical and other related substances, among other factors.

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA

section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the various fragrance components identified in Unit II of this document, including exposure resulting from the exemptions established by this action. EPA's assessment of exposures and risks associated with these various fragrance components follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by the various fragrance components identified in Unit II, as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies, are discussed in this unit.

The Agency assessed these fragrance components via the Threshold of Toxicological Concern (TTC) approach as outlined by the European Food Safety Authority (EFSA) in their 2019 guidance document on the use of TTC in food safety assessment. Information regarding the database of studies and chemicals used to derive TTCs are reviewed therein. The TTC approach has been used by the Joint Expert Committee on Food Additives of the United Nations' (U.N.) Food and Agriculture Organization and the World Health Organization (JECFA), the former Scientific Committee on Food of the European Commission, the European Medicines Agency, and EFSA.

Information from JECFA reports as well as predictive toxicology using the Organisation for Economic Co-operation and Development (OECD) Quantitative Structure-Activity Relationships (QSAR) Toolbox was used to confirm that the fragrances listed in Unit II have low

carcinogenic potential and are thus good candidates for the application of the TTC method.

Although 27 chemicals had *in silico* carcinogenicity alerts, JECFA concluded and EPA concurs that all fragrances listed in Unit II have low carcinogenic potential, based on *in vitro* and/or *in vivo* genotoxicity studies available on the chemical or structurally related chemicals. Therefore, the TTC method can be applied to these fragrances.

TTCs are derived from a conservative and rigorous approach to establish generic threshold values for human exposure at which a very low probability of adverse effects is likely. By comparing a range of compounds by Cramer Class (classes I, II, and III which correspond to the probability of low, moderate and high toxicity) and NOEL (no-observed-effect-level), fifth percentile NOELs were established for each Cramer Class as “Human Exposure Thresholds”. These values were 3, 0.91 and 0.15 mg/kg/day for classes I, II, and III, respectively.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment->

pesticide-program.

The human exposure threshold value for threshold (*i.e.*, non-cancer) risks is based upon Cramer structural class. All of the fragrance components listed in Unit II are in Cramer Class I, which is defined as chemicals of simple structure and efficient modes of metabolism, suggesting low oral toxicity. Therefore, the NOEL of 3 mg/kg/day is selected as the point of departure for all exposure scenarios assessed (chronic dietary, incidental oral, dermal and inhalation exposures).

C. Exposure Assessment

1. *Dietary exposure.* In evaluating dietary exposure to each of the fragrance components listed in Unit II (*e.g.*, ingesting foods that come in contact with surfaces treated with pesticide formulations containing these fragrance components, and drinking water exposures), EPA considered exposure under the proposed exemptions at a concentration not to exceed 100 ppm for each of the listed fragrance components as well as any other sources of dietary exposure. EPA assessed dietary exposures from the fragrance components listed in Unit II in food as follows:

The dietary assessment for food contact sanitizer solutions calculated the Daily Dietary Dose (DDD) and the Estimated Daily Intake (EDI). The assessment considered application rates, residual solution or quantity of solution remaining on the treated surface without rinsing with potable water, surface area of the treated surface which comes into contact with food, pesticide migration fraction, and body weight. These assumptions are based on U.S. Food and Drug Administration guidelines.

2. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

The fragrance components listed in Unit II may be used as inert ingredients in products that are registered for specific uses that may result in residential exposure, such as pesticides

used in and around the home. The Agency conducted a conservative assessment of potential residential exposure by assessing various fragrance components in disinfectant-type uses (indoor scenarios). The Agency's assessment of adult residential exposure combines high-end dermal and inhalation handler exposure from indoor hard surface, wiping, and aerosol spray uses. The Agency's assessment of children's residential exposure includes total post-application exposures associated with contact with treated indoor surfaces (dermal and hand-to-mouth exposures).

3. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found the fragrance components listed in Unit II to share a common mechanism of toxicity with any other substances, nor do they appear to produce a toxic metabolite produced by other substances. For the purposes of the tolerance exemptions established in this rule, therefore, EPA has assumed that the fragrance components listed in Unit II do not have common mechanisms of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains

the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

The FQPA SF has been reduced to 1X in this risk assessment because clear NOELs and LOELs were established in the studies used to derive the endpoints (which included developmental and reproductive toxicity studies), maternal and developmental-specific 5th percentile NOELs indicate low potential for offspring susceptibility, and the conservative assumptions made in the exposure assessment are unlikely to underestimate risk.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute aggregate risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effects resulting from a single oral exposure were identified and no acute dietary endpoint was selected for any of the fragrance components listed in Unit II. Therefore, these fragrance components are not expected to pose an acute risk.

2. *Short-term aggregate risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). For residential handler short-term exposure scenarios, MOEs ranged from 140 to 2,500, while for residential post-application exposure scenarios, MOEs ranged from 380 to 7,400. These MOEs are greater than the level of concern (LOC) of 100 and therefore are not of concern. The short-term aggregate MOE is 109 for adults and 135 for children, which are greater than the LOC of 100 and therefore are not of concern.

3. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, the fragrance components listed in Unit II are not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in intermediate-term residential exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for these fragrance components.

4. *Chronic aggregate risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to the fragrance components listed in Unit II from food and water will utilize 19% of the cPAD for the U.S. population and 48% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Chronic residential exposure to residues of these fragrance components is not expected. Therefore, the chronic aggregate risk is equal to the chronic dietary exposure for children 1 to 2 years old (48% of the cPAD).

5. *Aggregate cancer risk for U.S. population.* There is low concern for genotoxicity/carcinogenicity in humans for the fragrance components listed in Unit II of this document. Therefore, the assessment under the TTC value for non-cancer risks is protective for all risks, including carcinogenicity.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to residues of the fragrance components listed in Unit II.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of the fragrance components listed in Unit II of this document in or on any food commodities. EPA is, however, establishing limitations on the amount of these fragrance components that may be used in antimicrobial pesticide formulations. These limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for food use that contains these fragrance components in excess of 100 ppm in the final pesticide formulation.

VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established for residues of the various fragrance components listed in Unit II of this document when used as inert ingredients (fragrance components) in pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils with an end-use concentration not to exceed 100 ppm under 40 CFR 180.940(a).

VII. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address

Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the National Government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 12, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.940 is amended by adding in alphabetical order the following inert ingredients to table 1 to paragraph (a):

- a. Bicyclo(2.2.1)heptan-2-ol, 1,3,3-trimethyl-
- b. Bicyclo(2.2.1)heptan-2-ol, 1,7,7-trimethyl-,propanoate, exo-
- c. Bicyclo[3.1.1]heptane, 6,6-dimethyl-2-methylene-
- d. Butanoic acid, 1,1-dimethyl-2-phenylethyl ester
- e. β -Caryophyllene
- f. Celery seed oil
- g. Citronellal
- h. Cyclohexene, 1-methyl-4-(1-methylethylidene)-
- i. p-Cymene
- j. 2-Decenal
- k. Dimethylbenzylcarbiny acetate

- l. Elemi oil (*Canarium* spp.)
- m. Ethyl (2E,4Z)-2,4-decadienoate
- n. Galbanum oil (*Ferula* spp.)
- o. 2-Hexenal, (2E)-
- p. 1H-Indole
- q. Isoborneol
- r. Isobornyl acetate
- s. Labdanum oil (*Cistus* spp.)
- t. laevo-Bornyl acetate
- u. Mace oil (*Myristica fragrans* Houtt.)
- v. Methyl anthranilate
- w. Methyl heptine carbonate
- x. 2-Methyl-3-(p-isopropylphenyl)propionaldehyde
- y. Methyl N-methylantranilate
- z. Methyl 2-nonenoate
- aa. Methyl 2-nonynoate
- bb. 2-Methyl-4-phenyl-2-butanol
- cc. p-Methylanisole
- dd. Nerolidol (isomer unspecified)
- ee. Nona-2-trans-6-cis-dienal
- ff. 2,6-Octadien-1-ol, 3,7-dimethyl-,(Z)-
- gg. Oil of lemon
- hh. Oil of lemongrass
- ii. Oils, clove
- jj. Oils, ginger
- kk. Oils, grapefruit

ll. Oils, lime

mm. Oils, orange, sweet, terpene-free

nn. Olibanum oil (Boswellia spp.)

oo. Oxacycloheptadec-10-ene-2-one

pp. Phenol, 2-methoxy-4-(2-propenyl)-

qq. 2-Phenylpropionaldehyde

rr. 2-Phenylpropionaldehyde dimethyl acetal

ss. α -Pinene

tt. Tangerine oil (Citrus reticulata blanco)

uu. γ -Terpinene

vv. 1,3,3-trimethyl-2-norbornanyl acetate

ww. Ylang-ylang oils.

The additions read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

Table 1 to Paragraph (a)

Pesticide Chemical	CAS Reg. No.	Limits
* *	* *	* *
Bicyclo(2.2.1)heptan-2-ol, 1,3,3-trimethyl-	1632-73-1	When ready for use, the end-use concentration is not to exceed 100 ppm
Bicyclo(2.2.1)heptan-2-ol, 1,7,7-trimethyl-,propanoate, exo-	2756-56-1	When ready for use, the end-use concentration is not to exceed 100 ppm
Bicyclo[3.1.1]heptane, 6,6-dimethyl-2-methylene-	127-91-3	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* *
Butanoic acid, 1,1-dimethyl-2-phenylethyl ester	10094-34-5	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* *
β -Caryophyllene	87-44-5	When ready for use, the end-use concentration is not to exceed 100 ppm
Celery seed oil	8015-90-5	When ready for use, the end-use

		concentration is not to exceed 100 ppm
* *	* *	* * *
Citronellal	106-23-0	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Cyclohexene, 1-methyl-4-(1-methylethylidene)-	586-62-9	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
p-Cymene	99-87-6	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
2-Decenal	3913-71-1	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Dimethylbenzylcarbinyl acetate	151-05-3	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Elemi oil (Canarium spp.)	8023-89-0	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Ethyl (2E,4Z)-2,4-decadienoate	3025-30-7	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Galbanum oil (Ferula spp.)	8023-91-4	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
2-Hexenal, (2E)-	6728-26-3	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
1H-Indole	120-72-9	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Isoborneol	124-76-5	When ready for use, the end-use concentration is not to exceed 100 ppm
Isobornyl acetate	125-12-2	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Labdanum oil (Cistus spp.)	8016-26-0	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
laevo-Bornyl acetate	5655-61-8	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Mace oil (Myristica fragrans Houtt.)	8007-12-3	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Methyl anthranilate	134-20-3	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Methyl heptene carbonate	111-12-6	When ready for use, the end-use

		concentration is not to exceed 100 ppm
* *	* *	* * *
2-Methyl-3-(p-isopropylphenyl)propionaldehyde	103-95-7	When ready for use, the end-use concentration is not to exceed 100 ppm
Methyl N-methylantranilate	85-91-6	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Methyl 2-nonenoate	111-79-5	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Methyl 2-nonynoate	111-80-8	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
2-Methyl-4-phenyl-2-butanol	103-05-9	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
p-Methylanisole	104-93-8	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Nerolidol (isomer unspecified)	7212-44-4	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Nona-2-trans-6-cis-dienal	557-48-2	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
2,6-Octadien-1-ol, 3,7-dimethyl-,(Z)-	106-25-2	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Oil of lemon	8008-56-8	When ready for use, the end-use concentration is not to exceed 100 ppm
Oil of lemongrass	8007-02-1	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Oils, clove	8000-34-8	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Oils, ginger	8007-08-7	When ready for use, the end-use concentration is not to exceed 100 ppm
Oils, grapefruit	8016-20-4	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Oils, lime	8008-26-2	When ready for use, the end-use concentration is not to exceed 100 ppm
Oils, orange, sweet, terpene-free	68606-94-0	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Olibanum oil (Boswellia spp.)	8016-36-2	When ready for use, the end-use concentration is not to exceed 100 ppm
* *	* *	* * *
Oxacycloheptadec-10-ene-2-one	28645-51-4	When ready for use, the end-use

		concentration is not to exceed 100 ppm
*	*	*
Phenol, 2-methoxy-4-(2-propenyl)-	97-53-0	When ready for use, the end-use concentration is not to exceed 100 ppm
*	*	*
2-Phenylpropionaldehyde	93-53-8	When ready for use, the end-use concentration is not to exceed 100 ppm
2-Phenylpropionaldehyde dimethyl acetal	90-87-9	When ready for use, the end-use concentration is not to exceed 100 ppm
*	*	*
α -Pinene	80-56-8	When ready for use, the end-use concentration is not to exceed 100 ppm
*	*	*
Tangerine oil (Citrus reticulata blanco)	8008-31-9	When ready for use, the end-use concentration is not to exceed 100 ppm
*	*	*
γ -Terpinene	99-85-4	When ready for use, the end-use concentration is not to exceed 100 ppm
*	*	*
1,3,3-trimethyl-2-norbornanyl acetate	13851-11-1	When ready for use, the end-use concentration is not to exceed 100 ppm
*	*	*
Ylang-ylang oils	8006-81-3	When ready for use, the end-use concentration is not to exceed 100 ppm
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